

Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1289, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the safety and efficacy of biologics license application 98-0286, Enbrel™ (etanercept, Immunex) for the treatment of rheumatoid arthritis.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 10, 1998. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 10, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 11, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-22572 Filed 8-21-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 17, 1998, 8 a.m. to 6 p.m., and September 18, 1998, 8 a.m. to 3:30 p.m.

Location: DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM-350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-3514, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 17, 1998, the committee will hear: (1) Updates on HCV nucleic acid testing; (2) year 2000 computer software; (3) recent review of albumin clinical trials; (4) informational summaries on the Hematopoietic/Progenitor Cell Products Workshop, Granulocytes for Transfusion Workshop, Nucleic Acid Testing for HCV and Other Viruses in Blood Donors Workshop; and (5) an informational presentation on TT virus and transfusion safety. In the afternoon, the committee will discuss and make recommendations on the Abbott Laboratories PRISM Detection Assay for HBsAg, Anti-HCV, and Anti-HTLV-I/II. On September 18, 1998, the committee will discuss and make recommendations on the topic of routine leukoreduction of blood components.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 4, 1998. On September 17, 1998, oral presentations from the public will be scheduled between approximately 3:30 p.m. and 4 p.m. and on September 18, 1998, between approximately 11:15 a.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 4, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 12, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Gas; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) (Nashville District Office) is announcing the following public workshop: Medical Gas Workshop. The topics to be discussed are current good manufacturing practice issues for the medical gas industry, including air liquefaction, transfilling, and hospital installations.

Date and Time: The public workshop will be held on Tuesday, October 27, 1998, 8 a.m. to 4:30 p.m.

Location: The public workshop will be held at the Holiday Inn Select, Nashville Opryland/Airport, 2200 Elm Hill Pike, Nashville, TN 37214. Maps to the public workshop location will be faxed upon request.

Contact: Kari L. Norton, Food and Drug Administration, 297 Plus Park Blvd., Nashville, TN 37217, 615-781-5380, ext. 112, FAX 615-781-5391, or e-mail "knorton@ora.fda.gov".

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by Friday, October 2, 1998. Please include "Medical Gas Workshop Registration" in the subject line. There is no registration fee for this public workshop. Space is limited to 150 registrants, and further limited to 2 attendees per firm. Firms desiring more than two slots may be accommodated if there are vacancies.

If you need special accommodations due to a disability, please contact Kari L. Norton at least 7 days in advance.

Dated: August 11, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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